Surgical Instrument Service Co., Inc.

da Vinci® EndoWrist® Repair FAQs

Can you send me your certification / FDA approval?

The FDA does not regulate, nor certify, repairs. The FDA regulates third party reprocessing companies and single-use devices only.

What does your service provide?

SIS's service is a complete repair of the da Vinci® EndoWrist® instruments. The instruments are sold with a use counter which limits the life of the instrument. Upon reaching a zero count the instruments are "expired" and rendered useless.

This service includes resetting the use counter via a replacement chip as well as a complete evaluation and repair of the distal/tool end of the instrument. The replacement chips, as well as the service process, were designed and developed under a formal quality system ensuring the serviced instruments meet the quality and functional requirements of a new device. Formal, independent testing and validation on the replacement chips were conducted to ensure the intended use and performance are equivalent to that of the new OEM device.

What do we need to know to collect instruments for service?

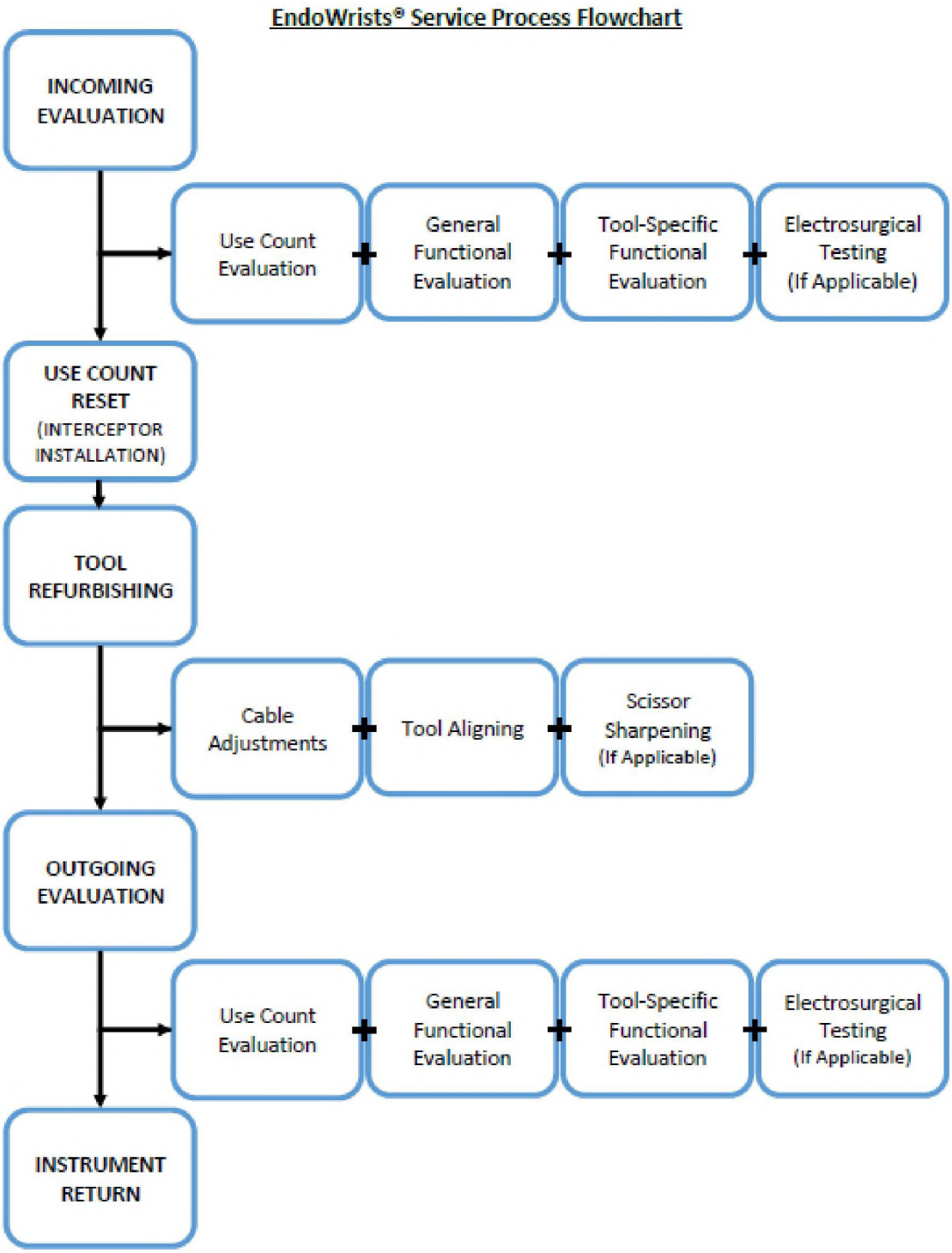
Upon receiving an instrument for the initial repair, the instrument must have at least one use left on the counter. If the original instrument reaches zero (0) it cannot be serviced. In order for the reset to be performed, the data must be retained on the initial repair. However, once the reset has been performed once, the instrument can be used up to expiration (zero) and still retain its original data and the ability to be reset.

What instrument models are supported?

Compatible EndoWrist® Instruments

420001 Potts Scissors
420003 Small Clip Applier
420006 Large Needle Driver
420007 Round Tip Scissors
420033 Black Diamond Micro Forceps
420036 DeBakey Forceps
420048 Tip Forceps
420049 Cadiere Forceps
420093 ProGrasp Forceps
420110 PreCise Bipolar Forceps
420121 Fine Tissue Forceps
420157 Snap-fit™ Scalpel Instrument
420171 Micro Bipolar Forceps
420172 Maryland Bipolar Forceps
420178 Curved Scissors
420179 Hot Shears (Monopolar Curved Scissors)
420181 Resano Forceps
420183 Permanent Cautery Hook
420184 Permanent Cautery Spatula
420189 Double Fenestrated Grasper
420190 Cobra Grasper
420192 Valve Hook
420194 Mega Needle Driver (Tapered)
420203 Pericardial Dissector
420204 Atrial Retractor
420205 Fenestrated Bipolar Forceps
420207 Tenaculum Forceps
420215 Cardiac Probe Grasper
420227 PK® Dissecting Forceps
420230 Large Clip Applier
420246 Atrial Retractor Short Right
420249 Dual Blade Retractor
420278 Graptor (Grasping Retractor)
420296 Large SutureCut™ Needle Driver
420309 Mega™ SutureCut™ Needle Driver
420318 Small Graptor (Grasping Retractor)
420327 Medium-Large Clip Applier
420344 Curved Bipolar Dissector

Can you describe your service process?



Additional information:

- EndoWrist® functionality and safety are not affected by the repair
    - Extensive analysis and formal testing were performed to ensure the proper function and performance
    - Repaired instruments have been subjected to, and passed, all appropriate ISO 10993 biocompatibility tests (by a certified independent test laboratory)
    - Electrical and electrosurgical safety have been carefully considered per the expectations in the safety standards, and special fixtures are used during service to retest the instrument to a production equivalent qualification

- Service components are built to medical device quality standards, including:
    - ISO 9001: Quality Systems Model for QA in Design/Development, Production, Installation, and Servicing
    - ISO 9002: Quality Systems Model for QA in Production and Installation
    - ISO 9003: Quality Systems Model for QA in Final Inspection and test
    - ISO 9001: Quality Management Systems

- The service process is performed under a formal quality control system certified per ISO 9001, with all assembly operations and testing performed per formal procedures

- SIS provides continuing technical support to assure the final quality of the serviced instruments, and will monitor and respond to any reported field issues using a formal surveillance system

- Validated fixtures and tools can be provided to repeat safety testing in the hospital, if desired

da Vinci® EndoWrist® Repairs

Stop throwing away money on your da Vinci® EndoWrist® devices!

SIS can now service your da Vinci® devices including repair and use counter reset.

Important facts:

- The da Vinci® EndoWrist® is a "multi-use" medical device. Multi-use devices, such as endoscopic instruments, have always been eligible for repair.
- The repair of da Vinci® EndoWrist® does not alter the intended use, method of use, functionality or performance of the device in any way.
- The da Vinci® Robot interacts with the repaired EndoWrist® identically and the robot cannot be affected by the repaired device in any way.
- The robot communicates with the EndoWrist® prior to surgery only. Prior to surgery, the robot confirms the serial number, model number and remaining uses. The repaired device will function identically to the new OEM EndoWrist®.
- A repaired EndoWrist® is not an alternative or replacement device. It is an original da Vinci® manufactured device that has been repaired to original specifications.

It's time to challenge the status quo

SIS da Vinci® EndoWrist® repair services will boost your bottom line and help provide the prompt and tailored responses your OR demands.

Call your local SIS representative or our Corporate Office at 800.747.8044.

da Vinci® EndoWrist® Repair Process

When sending in your DaVinci EndoWrist® devices to SIS for repair, it is important to follow all the instructions below.

All devices must go through the decontamination process before they are collected for service by SIS. The devices do not need to be sterile.

Initial Service on an EndoWrist® (Si & S) Device

- The EndoWrist® must be sent in with one click remaining. This is only required for the initial service of the EndoWrist®. Once the device has been serviced by SIS, the counter can be run to zero.
- If an EndoWrist® is being sent for its initial service with SIS, place a red sticker on the body of the device.
- Place EndoWrist® into the SIS collection container
- Devices will be collected by your local SIS representative and shipped to the SIS National Service Center.
- Devices will be tested, refurbished to OEM performance specifications, and reset for 10 additional uses. During the refurbishment process, a code will be etched on the device.
- Once repaired, the device will be returned to your facility by your local SIS representative.

Ongoing Service of EndoWrist® (Si & S) Devices (applies only to devices that have been previously serviced by SIS)

- Device to be collected with zero clicks remaining (device is "expired")
- Place EndoWrist® into the SIS collection container
- Devices will be collected by your local SIS representative and shipped to the SIS National Service Center.
- Devices will be tested, refurbished to OEM performance specifications, and reset for 10 additional uses.
- Once repaired, the device will be returned to your facility by your local SIS representative.

EndoWrist® (Xi, Si & S) Device Collection for Parts and Testing

- All Xi devices
- Si and S devices that have zero clicks or have expired and not been serviced prior by SIS (not etched)
- Place devices in the SIS collection container
- Devices will be collected by your local SIS representative and shipped to the SIS National Service Center.

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Summary of Quality and Reliability Measures

BACKGROUND

SIS da Vinci® repair is a specialized process for the EndoDevice® instruments of the da Vinci® surgical robot to extend their safe and effective life beyond the uses recommended by the original equipment manufacturer. SIS services the devices by installing a resettable use counter while maintaining the ability of the da Vinci™ Surgical Robot to access all data in the OEM memory and to count uses as usual.

These devices are not single use devices. The materials in the instruments are durable and commonly used in other reusable medical devices. Testing of the instruments after many additional usage cycles indicated no trend of material deterioration beyond normal tool wear.

The intended use, method of use, functionality, or performance of the instrument are not changed by this service. The original data required by the machine to communicate with the instrument is not altered in any way. The machine will still recognize the model number, serial number, and instrument being used. Additionally, the data read from the instrument is clearly displayed and verified by the user and robot prior to surgery. Data is not read during surgery.

QUALITY SYSTEM INFORMATION

The quality management system has been approved by the notified body DQS Medizinprodukte GmbH according to ISO 13485:2003 and MDD 93/42/EEC MOD 5 compliant system.

The quality management system has been approved and is currently certified by the notified body Global Group according to ISO 9001:2015.

SERVICE PROCESS DEVELOPMENT

The da Vinci® S/Si instruments are sold with an arbitrary use counter, which limits usage to a certain number of procedures. Upon reaching zero, the instruments are considered “expired” and must be discarded. Our service provides the ability to extend the useful life of the instrument. The service process involves a complete evaluation, repair, and test of the instrument.

The SIS EndoWrist® service was designed for the da Vinci® S/Si Device Instruments, the OEM chip, and robot interface to perform in the same manner as the OEM original. This service does not affect the instruments form, fit or function.

The applicable products are outlined on the following pages (this list may be updated as new products are approved for repair):

REF	USES	DESCRIPTION
420001	10	Potts Scissors
420003	100	Small Clip Applier
420006	10	Large Needle Driver
420007	10	Round Tip Scissors
420033	15	Black Diamond Micro Forceps
420036	10	DeBakey Forceps
420048	10	Long Tip Forceps
420049	10	Cadiere Forceps
420093	10	ProGrasp Forceps
420110	10	PreCise Bipolar Forceps
420121	15	Fine Tissue Forceps
420157	30	Snap-fit™ Scalpel Instrument

420171	10	Micro Bipolar Forceps
420172	10	Maryland Bipolar Forceps
420178	10	Curved Scissors
420179	10	Hot Shears (Monopolar Curved Scissors)
420181	10	Resano Forceps
420183	10	Permanent Cautery Hook
420184	10	Permanent Cautery Spatula
420189	10	Double Fenestrated Grasper
420190	10	Cobra Grasper
420192	15	Valve Hook
420194	10	Mega Needle Driver (Tapered)
420203	10	Pericardial Dissector
420204	10	Atrial Retractor

420205	10	Fenestrated Bipolar Forceps
420207	10	Tenaculum Forceps
420215	10	Cardiac Probe Grasper
420227	10	PK® Dissecting Forceps
420230	100	Large Clip Applier
420246	10	Atrial Retractor Short Right
420249	10	Dual Blade Retractor
420278	10	Graptor (Grasping Retractor)
420296	10	Large SutureCut™ Needle Driver
420309	10	Mega™ SutureCut™ Needle Driver
420318	10	Small Graptor (Grasping Retractor)
420327	100	Medium-Large Clip Applier
420344	10	Curved Bipolar Dissector

Risk Management

Risk management activities per ISO 14971 standard were performed during the development, verification and validation of service processes. Post-production monitoring of the devices serviced by SIS will ensure this service remains free from safety concerns. The risk management process identifies, estimates, and evaluates the serviced product's safety risks, methods to control these risks, and to verify the effectiveness of these controls. A detailed FMEA (Failure Modes and Effects Analysis) was performed covering the
service process.

Development Process

Extensive validation and safety testing occurred during the development of the service process (see below). Both the development of the service process and the ongoing repair operations are performed under the appropriate certified quality systems. A complete technical file describing qualification activities and independent testing was created and informed the development of formal procedures to guide the service operations performed.

The following list of standards was considered and applied to the development process:

Standard #	Year	Title
EN 980	2008	Symbols for use in the labeling of medical devices
EN 1041	2008	Information supplied by the manufacturer of medical devices
EN ISO 10993-1	2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-4	2009	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
EN ISO 10993-5	2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10	2010	Biological evaluation of medical devices – Part 10: Tests for Irritation and Skin Sensitization
EN ISO 10993-11	2009	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity

EN ISO 10993-12	2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
EN ISO 13485	2012 & AC: 2012	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971	2012	Application of risk management to medical devices
EN ISO 14937	2009	Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
EN ISO 17664	2004	Sterilization of medical devices – Information to be provided by the manufacturer for the processing of re-sterilizable medical devices
EN ISO 17665-1	2006	Sterilization of health care products – Moist Heat – Part 1: Requirements for the development, validation and routine control of a sterilizer for medical devices (reference only)
EN ISO 17665-2	2009	Sterilization of health care products – Moist Heat – Part 2: Guidance on the application of ISO 17665-1 (reference only)
EN 60601-1	2006	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1-2	2007	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
EN 60601-2-2	2009	Medial electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
EN 62304	2006	Medical device software – Software life-cycle processes
EN 62366	2008	Medical devices – Application of usability engineering to medical devices

BIOLOGICAL EVALUATION

The material and microbiological characteristics of devices that have been serviced have been evaluated to determine whether they demonstrate any biocompatibility risk. It has been assumed that the OEM devices were marketed as biocompatible.

Tests were conducted with devices serviced to demonstrate compliance to the following standards:

Test	Standard	Report #
ISO MEM Elution Assay with L-929 Mouse Fibroblast Cells	• ISO 10993-5: 2009 Biological Evaluation of Medical Devices, Part 5: Tests for In Vitro Cytotoxicity • ISO 10993-12: 2012 Biological Evaluation of Medical Devices, Part 12: Sample Preparation and Reference Materials	5107 and 5109
ASTM Hemolysis – Extract Method (GLP)	• ASTM Guideline F619-03, reapproved 2008. Standard Practice for Extraction of Medical Plastics. 2012. Annual Book of ASTM Standards, Volume 13.01:223-226 • ISO 10993-4: 2002 and Amendment 1, 2006. Biological Evaluation of Medical Devices, Part 4: Selection of Tests for Interaction with Blood • ISO 10993-12: 2012 Biological Evaluation of Medical Devices, Part 12: Sample Preparation and Reference Materials	4349 and 4350
ISO Guinea Pig Maximization Sensitization Test (GLP-2 Extracts)	• ISO 10993-10: 2010 Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization, pp. 18-26 • ISO 10993-12: 2012 Biological Evaluation of Medical Devices, Part 12: Sample Preparation and Reference Materials	5003 and 4981
ISO Acute Systemic Injection Test (GLP-2 Extracts)	• ISO 10993-11: 2006 Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity • ISO 10993-12: 2012 Biological Evaluation of Medical Devices, Part 12: Sample Preparation and Reference Materials	4498 and 4501

ISO Intracutaneous Irritation Test (GLP-2 Extracts)	• ISO 10993-10: 2010 Standard, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization, pp. 11-14	4316 and 4317
	• ISO 10993-12: 2012 Biological Evaluation of Medical Devices, Part 12: Sample Preparation and Reference Materials	

The test results revealed no unacceptable levels of toxicity or irritation. All test samples demonstrated the necessary biocompatibility characteristics.

Cleaning and sterilization

The serviced devices are not provided in a sterile condition. However, they do require cleaning and sterilization prior to clinical use per the OEM IFU. There are no changes to these processes, which are performed between surgeries at the hospital. In order to ensure that sterilization instructions remain valid for the devices serviced, they have completed both cleaning and sterilization qualification studies. These studies were performed by a third party specializing in the cleaning and sterilization processes. The final results demonstrate that the recommended procedures ensure adequate cleaning and sterilization for end users of the devices.

ELECTRICAL AND ELECTROSURGICAL SAFETY

Electrical/Electrosurgical safety testing has been conducted using a third party independent test lab to verify serviced devices meet applicable environmental, safety and labeling requirements.

Tests were performed using devices serviced to demonstrate compliance to the standards listed on the following page:

Standard Document	Description
IEC 60601-1: 2005 & A1: 2012	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-2-2: 2009	Medical Electrical Equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
EN 60601-1-2: 2007	Medical Electrical Equipment: General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests.

The results demonstrate compliance with the applicable requirements of the aforementioned safety standards for medical devices.

USABILITY ENGINEERING

The services have been designed to maintain the exterior specification, connection, use application, user profile, or frequently used functions, when compared to the original devices produced by the OEM. We have considered the impact of the safety and labeling requirements for the end users. One additional challenge to the labeling integrity was conducted during the electrical safety testing by SGS. Those results demonstrated legibility following an intentional rub down test.

RELIABILITY/PERFORMANCE TEST SUMMARY

A worst-case analysis was carried out to determine which models should be used during performance and life testing. Although each tool is unique, there are four basic mechanical function/tool end designs: Scissors, Graspers, Needle Drivers and Non-Opening (tool ends that do not open and close).

In addition, certain models deliver RF energy (“Energized Device”). Energized Devices are either Monopolar, Bipolar or PlasmaKinetic™ (PK™). For each Tool End Design, an Energized Device is considered worst case because RF energy represents a greater stress/challenge to the tool end. Representative models

were chosen based on Tool End Design, Energized Device models and general market popularity.

Initially, a quantity of each representative model was characterized by their mechanical and functional properties. New OEM instruments were analyzed to provide baseline statistics and information. Examples of such statistics include, but were not limited to:

- Tool end range of motion
- Tool end functional performance (e.g. grasping performance and cutting performance)
- RF energy effectiveness
- Electrical safety testing
- General instrument condition
- Effective communication and use counting on the host system

Following the OEM characterization, instruments with one remaining use underwent the repair process. Immediately following the repair process, the instruments were subjected to the same baseline testing in order to establish equivalence. Formal life-testing was then conducted to simulate an additional 10 uses. The life testing subjected the instrument to 10 simulated surgical environments to test each aspect of the individual instrument's functional capabilities. After each of the simulated uses, the instruments were subjected to the normal cleaning and sterilization procedures provided by the OEM. At different intervals, and at end-of-life, the instrument was subjected to the same battery of testing. The testing showed no degradation in performance or condition of the instruments. The formal protocols executed reside in the technical file per the ISO 13485 quality system used for development; these files were independently reviewed by DQS, a certified EU notified body assessor for medical devices.

Additionally, this repair process was repeated and a battery of tests was performed on the same batch of instruments. This brought the total number of uses experienced by the instruments to 29. This includes the 9 original uses on the OEM device, 10 additional uses following first repair service, and another 10 uses following the second repair process. The reliability testing following two repair services showed no trend of degradation in the performance or condition

of the instruments, therefore no further cycles under this formal protocol were conducted.

The test results revealed that all acceptance criteria have been achieved and the sample devices demonstrate sufficient performance and safety characteristics in order to confidently release the devices to distribution. Also, a worst-case verification test has been performed on the flush tube, a component of all devices, to ensure it has been adequately challenged in an effort to confirm the environmental conditions of use do not adversely affect the component and related performance expectations.

During further analysis for reliability, disassembled OEM instruments and their components underwent material analysis by experts in medical device design and construction. The instruments' materials were surgical grade metals or well-established thermoplastics already being utilized in other multiple-use surgical instruments.

Following the formal testing described above, a smaller batch of representative models were subjected to over 50 cleaning and sterilization cycles to demonstrate the robust nature of the instrument's design. Similar inspection and testing was carried out on these devices, and, as expected, no indications of material degradation were
observed.

FUNCTIONAL VERIFICATION AND VALIDATION

Approach

Several compatibility and functional validations were conducted of the replacement chip for use with the da Vinci® S and da Vinci® Si Surgical Systems. Such validations included utilizing OEM instruments to characterize the timing and types of communications between the instrument and the host system. These same instruments were then repaired, and the replacement chip installed. The repaired instruments were then subjected to the same characterization on the same host systems to validate their equivalence. These validations showed equivalence in all instrument models and on both the S and Si Surgical Systems.

Functional testing included extensive formal protocols following regulatory expectations for medical device software testing (there is no software inside the instrument, but it interfaces to the software inside the robot itself via a simple data bus). Reputable third-party experts were utilized to ensure rigorous and independent validation.